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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,644	09/27/2001	Mark W. Bitensky	S-092701	3052

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EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/965,644	Applicant(s) BITENSKY ET AL.	
	Examiner Teresa E. Strzelecka	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,12-17 and 47-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,4,12-16,47 and 49 is/are allowed.
- 6) ☒ Claim(s) 5-8,17,48 and 50-53 is/are rejected.
- 7) ☒ Claim(s) 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on April 17, 2006 has been entered.

2. Claims 1-46 were previously pending, with claims 19-46 withdrawn from consideration. Applicants cancelled claims 2, 9-11 and 18-46, amended claims 1, 3-8, 12, 13 and added new claims 47-53. Claims 1, 3-8, 12-17 and 47-53 are pending and will be examined.

3. Applicants' amendments overcame the following rejections: rejection of claims 1-18 under 35 U.S.C. 102(b) as anticipated by Sutton et al. and rejection of claims 1, 2, 5-15, 17 and 18 under 35 U.S.C. 102(b) as anticipated by Brody et al.

4. This office action contains new grounds for rejection.

Claim Objections

5. Claim 53 is objected to because of the following informalities: "microchannel have an entry portion" is grammatically incorrect. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 5-8 and 50-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A) Applicants amended claim 5 to include the limitation of the channel length between 50 and 70 microns, channel entry width between 3.5 and 4.0 microns and exit width between 1.0 and 2.0 microns and channel depth between 3.2 and 3.6 microns. There is no support in the specification or the original claims for these limitations. For example, the original channel length claimed was about 60 microns. However, since Applicants did not define what range of widths corresponds to the term “about”, about 60 microns could be interpreted as 20 microns, for example. Therefore, the limitation “about 60 microns” does not provide support for the range of 50 to 70 microns without the definition of the term “about”. The same applies to the claimed ranges of channel entry and exit widths and channel depth.

B) Applicants amended claim 6 to include the limitation of the channel length between 30 and 37 microns, channel entry width between 3.4 and 3.8 microns and exit width between 1.2 and 1.6 microns. There is no support in the specification or the original claims for these limitations. For example, the original channel length claimed was about 35 microns. However, since Applicants did not define what range of widths corresponds to the term “about”, about 35 microns could be interpreted as 20 microns, for example. Therefore, the limitation “about 35 microns” does not provide support for the range of 30 to 37 microns without the definition of the term “about”. The same applies to the claimed ranges of channel entry and exit widths.

C) Applicants amended claim 7 to include the limitation of the channel length between 95 and 105 microns, channel entry width between 4.3 and 4.7 microns and exit width between 1.3 and 1.7 microns. There is no support in the specification or the original claims for these limitations. For example, the original channel length claimed was about 100 microns. However, since Applicants

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did not define what range of widths corresponds to the term “about”, about 100 microns could be interpreted as 20 microns, for example. Therefore, the limitation “about 100 microns” does not provide support for the range of 95 to 105 microns without the definition of the term “about”. The same applies to the claimed ranges of channel entry and exit widths.

D) Applicants amended claim 8 to include the limitation of the channel length between 14 and 18 microns, channel entry width between 3.4 and 3.8 microns and exit width between 1.2 and 1.6 microns. There is no support in the specification or the original claims for these limitations. For example, the original channel length claimed was about 16 microns. However, since Applicants did not define what range of widths corresponds to the term “about”, about 16 microns could be interpreted as 2 microns, for example. Therefore, the limitation “about 16 microns” does not provide support for the range of 14 to 18 microns without the definition of the term “about”. The same applies to the claimed ranges of channel entry and exit widths.

E) The newly added claim 50 is drawn to a microchannel which has an area that is similar to the area of a human capillary. There is no support in the specification or in the original claims for this limitation.

F) The newly added claim 51 is drawn to microchannels which have an area that is larger than the area of a human capillary. There is no support in the specification or in the original claims for this limitation.

G) The newly added claim 52 contains a limitation of wedge shaped microchannel which have an area that is similar to the area of a human capillary and non-wedge shaped microchannels in the same row have an area that is wider than the cell to be analyzed. There is no support in the specification or in the original claims for this limitation.

H) The newly added claim 53 is drawn to a wedge shaped microchannel which has an entry portion that is larger than human capillary and an exit portion that is smaller than a human capillary. There is no support in the specification or in the original claims for this limitation.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 17, 48 and 50-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 17 is indefinite over the recitation of “wherein said microchannels have dimensions on the same scale as human capillaries.” Applicants did not provide any numerical values for the sizes of human capillaries, i.e., length and diameter, therefore it is not clear what the dimensions of the microchannels should be if they are to be “on the same scale” as human capillaries.

B) Claim 48 is indefinite over the recitation of “wherein the dimensions of the wedge-shaped microchannel are defined by area and volume, wherein the area and volume of a cell are known and the length, width and height of the microchannel is varied so that a target blood cell may enter, but not exit”. There is insufficient antecedent basis for this limitation in the claim. Claim 1, from which claim 48 depends, does not contain limitations of wedge-shaped microchannels.

C) Claim 50 is indefinite over the recitation of “wherein the microchannel has an area that is similar to the area of a human capillary”. First, the microchannel is a three-dimensional entity, therefore it can have at least two different cross-sectional areas, and it is not clear which one of those is considered. Second, an area of human capillary has at least three different meanings: either a cross-sectional area perpendicular to the capillary length, or a cross-sectional area parallel to the

capillary's length, or a total surface area of a capillary. It is not clear which one of these areas Applicants are contemplating. Finally, Applicants did not provide any numerical values for the sizes of human capillaries, i.e., length and diameter, therefore it is not clear what the areas claimed would be.

D) Claim 51 is indefinite over the recitation of "wherein the microchannels have an area that is larger than the area of a human capillary". First, the microchannel is a three-dimensional entity, therefore it can have at least two different cross-sectional areas, and it is not clear which one of those is considered. Second, an area of human capillary has at least three different meanings: either a cross-sectional area perpendicular to the capillary length, or a cross-sectional area parallel to the capillary's length, or a total surface area of a capillary. It is not clear which one of these areas Applicants are contemplating. Finally, Applicants did not provide any numerical values for the sizes of human capillaries, i.e., length and diameter, therefore it is not clear what the areas claimed would be.

E) Claim 52 is indefinite over the recitation of "wherein the wedge shaped microchannels have a three dimensional entry portion that is wider than a three dimensional exit portion and wherein the area of the wedge-shaped microchannel is similar to the area of a human capillary, and wherein the non-wedge shaped microchannels in the same row have an area that is wider than the cell to be analyzed." First, the microchannel is a three-dimensional entity, therefore it can have at least two different cross-sectional areas, and it is not clear which one of those is considered. Second, an area of human capillary has at least three different meanings: either a cross-sectional area perpendicular to the capillary length, or a cross-sectional area parallel to the capillary's length, or a total surface area of a capillary. It is not clear which one of these areas Applicants are contemplating. Also, it is not clear how an area can be "wider" than a cell, since "wider" refers to a

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single dimension, whereas an area is a two-dimensional object. Finally, Applicants did not provide any numerical values for the sizes of human capillaries, i.e., length and diameter, therefore it is not clear what the areas claimed would be.

F) Claim 53 is indefinite over the recitation of “wherein the wedge shaped microchannel have an entry portion that is larger than a human capillary and an exit portion that is smaller than a human capillary”. Applicants did not provide any numerical values for the sizes of human capillaries, i.e., length and diameter, therefore it is not clear what the claimed dimensions would be.

Allowable Subject Matter

10. No references were found teaching or suggesting claims 1, 3-8, 12-17 and 47-53.
11. Claims 5-8, 17, 48 and 50-53 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first and second 2nd paragraph, set forth in this Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

Teresa Strzelecka

6/23/06